

However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 1,825 days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may, on or before September 18, 1995, submit to the Dockets Management Branch (address above) written comments and ask for a redetermination. Furthermore, any interested person may petition FDA, on or before January 15, 1996, for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41-42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Comments and petitions should be submitted to the Dockets Management Branch (address above) in three copies (except that individuals may submit single copies) and identified with the docket number found in brackets in the heading of this document. Comments and petitions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: June 30, 1995.

Stuart L. Nightingale,

Associate Commissioner for Health Affairs.

[FR Doc. 95-17504 Filed 7-17-95; 8:45 am]

BILLING CODE 4160-01-F

[Docket No. 95M-0178]

**Polymer Technology Division of
Wilmington Partners L.P.; Premarket
Approval of Boston Simplicity™**

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing its approval of the application by Polymer Technology Division of Wilmington Partners L.P., Wilmington, MA, for premarket approval, under the Federal Food, Drug, and Cosmetic Act (the act), of BOSTON Simplicity™. FDA's Center for Devices and Radiological Health (CDRH) notified the applicant, by letter on June 9, 1995, of the approval of the application.

DATES: Petitions for administrative review by August 17, 1995.

ADDRESSES: Written requests for copies of the summary of safety and

effectiveness data and petitions for administrative review to the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

David M. Whipple, Center for Devices and Radiological Health (HFZ-460), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-594-1744.

SUPPLEMENTARY INFORMATION: On March 6, 1995, Polymer Technology Division of Wilmington Partners L.P., Wilmington, MA 01887, submitted to CDRH an application for premarket approval of BOSTON Simplicity™. The device is a cleaning, rinsing, disinfecting and conditioning solution and is indicated for cleaning, rinsing, disinfecting and conditioning fluoro silicone acrylate and silicone acrylate rigid gas permeable contact lenses.

In accordance with the provisions of section 515(c)(2) of the act (21 U.S.C. 360e(c)(2)) as amended by the Safe Medical Devices Act of 1990, this premarket approval application (PMA) was not referred to the Ophthalmic Devices Panel of the Medical Devices Advisory Committee, an FDA advisory committee, for review and recommendation because the information in the PMA substantially duplicates information previously reviewed by this panel.

On June 9, 1995, CDRH approved the application by a letter to the applicant from the Director of the Office of Device Evaluation, CDRH.

A summary of the safety and effectiveness data on which CDRH based its approval is on file in the Dockets Management Branch (address above) and is available from that office upon written request. Requests should be identified with the name of the device and the docket number found in brackets in the heading of this document.

Opportunity for Administrative Review

Section 515(d)(3) of the act authorizes any interested person to petition, under section 515(g) of the act, for administrative review of CDRH's decision to approve this application. A petitioner may request either a formal hearing under part 12 (21 CFR part 12) of FDA's administrative practices and procedures regulations or a review of the application and CDRH's action by an independent advisory committee of experts. A petition is to be in the form of a petition for reconsideration under § 10.33(b) (21 CFR 10.33(b)). A petitioner shall identify the form of

review requested (hearing or independent advisory committee) and shall submit with the petition supporting data and information showing that there is a genuine and substantial issue of material fact for resolution through administrative review. After reviewing the petition, FDA will decide whether to grant or deny the petition and will publish a notice of its decision in the **Federal Register**. If FDA grants the petition, the notice will state the issue to be reviewed, the form of review to be used, the persons who may participate in the review, the time and place where the review will occur, and other details.

Petitioners may, at any time on or before August 17, 1995, file with the Dockets Management Branch (address above) two copies of each petition and supporting data and information, identified with the name of the device and the docket number found in brackets in the heading of this document. Received petitions may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (secs. 515(d), 520(h) (21 U.S.C. 360e(d), 360j(h))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Director, Center for Devices and Radiological Health (21 CFR 5.53).

Dated: July 10, 1995.

Joseph A. Levitt,

Deputy Director for Regulations Policy, Center for Devices and Radiological Health.

[FR Doc. 95-17642 Filed 7-17-95; 8:45 am]

BILLING CODE 4160-01-F

**Health Resources and Services
Administration**

**Program Announcement for
Scholarships for Disadvantaged
Students**

The Health Resources and Services Administration (HRSA) announces that applications for fiscal year (FY) 1995 Scholarships for Disadvantaged Students (SDS) program are being accepted under the authority of section 737 of the Public Health Service Act (the Act), title VII, Part B, as amended by the Health Professions Education Extension Amendments of 1992, Pub. L. 102-408, dated October 13, 1992. Schools that received funds for academic year 1994-95 will be funded based on the information provided in last year's application, and do not need to reapply.

Purpose

The SDS program is a program of grants to health professions and nursing schools for the purpose of assisting such schools in providing scholarships to individuals from disadvantaged backgrounds who are enrolled (or accepted for enrollment) as full-time students in the schools, as well as to undergraduate students who have demonstrated a commitment to pursuing a career in health professions.

For purposes of the SDS program in FY 1995, an "individual from disadvantaged background" is defined in 42 CFR 57.1804, subpart S, as one who:

(1) Comes from an environment that has inhibited the individual from obtaining the knowledge, skill, and abilities required to enroll in and graduate from a health professions school, or from a program providing education or training in allied health professions; or

(2) Comes from a family with an annual income below a level based on low-income thresholds according to family size published by the U.S. Bureau of the Census, adjusted annually for changes in the Consumer Price Index, and adjusted by the Secretary for use in all health professions and nursing programs. The Secretary will periodically publish these low-income levels in the **Federal Register**.

The following income figures determine what constitutes a low-income family for purposes of the Scholarships for Disadvantaged Students program for FY 1995.

| Size of parents' family ¹ | Income level ² |
|--------------------------------------|---------------------------|
| 1 | \$10,000 |
| 2 | 12,900 |
| 3 | 15,400 |
| 4 | 19,700 |
| 5 | 23,200 |
| 6 or more | 26,100 |

¹ Includes only dependents listed on Federal income tax forms.

² Adjusted gross income for calendar year 1994, rounded to nearest \$100. These low income figures are published in this issue of the **FEDERAL REGISTER**.

Approximately \$18 million is available in FY 1995 for competing applications for the SDS Program from eligible health professions and nursing schools. Of the funds available, 30 percent shall be made available to schools agreeing to expend the grants only for nursing scholarships. An estimated \$5.4 million will support approximately 3,600 scholarships averaging \$1,500 for students at schools of nursing. The balance of \$12.6 million

will support approximately 5,040 scholarships averaging \$2,500 for eligible health professions students. The period of fund availability will be for one academic year.

Use of Funds

Funds awarded to a school under this program may be used as follows:

(1) To award scholarships to eligible students enrolled in the school, to be expended only for tuition expenses, other reasonable educational expenses, and reasonable living expenses (as defined by the school for all students attending the school) incurred while enrolled in a school as a full-time student. The amount of the scholarship may not, for any year of attendance, exceed the total amount required for the year for the expenses specified above.

(2) To provide financial assistance to undergraduate students who have demonstrated a commitment to pursuing a career in the health professions, in order to facilitate the completion of the educational requirements for such careers, provided that the total amount used for this purpose may not exceed 25 percent of the funds awarded to the school under this program.

Any school receiving SDS funds will be required to maintain separate accountability for these funds.

School Eligibility

Grants under this program will be made available to accredited public or nonprofit private health professions schools. For purposes of the SDS program, as defined in section 737(a)(3) of the Act, the term "health professions schools" means schools of medicine, nursing, osteopathic medicine, dentistry, pharmacy, podiatric medicine, optometry, veterinary medicine, public health, or allied health or schools offering graduate programs in clinical psychology and which are accredited as provided in section 799(1)(E) of the Act, schools of allied health as defined in section 799(4) of the Act, and which are located in States as defined in section 799(9) of the Act, and schools of nursing as defined in section 853 of the Act.

As required by statute, to qualify for participation in the SDS program, a school must be:

(1) carrying out a program for recruiting and retaining students from disadvantaged backgrounds, including racial and ethnic minorities; and

(2) carrying out a program for recruiting and retaining minority faculty.

In addition, each school that received funds in FY 1994 must be carrying out

all of the statutory requirements listed below:

(1) Ensure that adequate instruction regarding minority health issues is provided for in the curricula of the school. This does not include normal course work, that by definition includes minority health issues (e.g., sickle cell anemia in a pathology class), but refers to course work reflecting an institutional awareness of the special health needs of minority populations;

(2) Enter into arrangements with one or more health clinics providing services to a significant number of individuals who are from disadvantaged backgrounds, including members of minority groups, for the purpose of providing students of the school with experience in providing clinical services to such individuals;

(3) Enter into arrangements with one or more public or nonprofit private secondary educational institutions and undergraduate institutions of higher education (feeder schools), for the purpose of carrying out programs regarding:

(a) the educational preparation of disadvantaged students, including minority students, to enter the health professions; and

(b) the recruitment of disadvantaged students, including minority students, into the health professions; and

(4) Establish a mentor program for assisting disadvantaged students, including minority students, regarding the completion of the educational requirements for degrees from the school. This program may include the involvement of students, community health professionals, faculty, alumni, past recipients of Health Career Opportunity Program (HCOP) funds, faculty/staff of feeder schools, etc., in institutionally organized activity (e.g., tutoring, counseling, and summer/bridge programs).

Each school funded for the first time in FY 1995 will also be required to carry out each of the activities specified above by not later than 12 months from receipt of award. Funds awarded to a school under the SDS program may not be used to carry out any of the above activities which the school must be doing, or must agree to do. In addition, a school will be required to continue to carry out all described activities, and also the student/faculty recruitment and retention activities, for as long as the SDS program is in operation in the school.

Evaluation Criteria for Fiscal Year 1995

For FY 1995, applications from newly participating schools will be evaluated on the degree to which the schools meet

the statutory requirements listed above. Guidance for presenting the information will be provided in the FY 1995 application materials. Schools that received funds for academic year 1994-95 will be funded based on the information provided in last year's application, and do not need to reapply.

Student Eligibility

As required by statute, to qualify for the SDS program, a student must:

(1) be a citizen, a U.S. national, an alien lawfully admitted for permanent residency in the U.S., or a citizen of the Commonwealth of the Northern Mariana Islands, a citizen of the Commonwealth of Puerto Rico, a citizen of the Republic of Palau, or a citizen of the Republic of the Marshall Islands or the Federated States of Micronesia;

(2) meet the definition of an "individual from a disadvantaged background" as defined above; and

(3)(a) be enrolled in or accepted by an eligible school for enrollment as a full-time student; or

(b) be an undergraduate student who has demonstrated a commitment to pursuing a career in health professions, including nursing.

Statutory Preference

The law requires that in providing SDS scholarships, the school give preference to students who are from disadvantaged backgrounds and for whom the cost of attending an SDS school would constitute a severe financial hardship. Severe financial hardship will be determined by the school in accordance with standard need analysis procedures prescribed by the Department of Education for its Federal student aid programs.

The following Criteria for Undergraduate Students, Definitions, Methodology for Implementing the Statutory Special Consideration, the Nonstatutory Special Consideration for Baccalaureate Nursing Programs, and the Procedures for Calculating Scholarship Awards were established in FY 1991 after public comment (at 57 FR 49779) on October 1, 1991, and are being extended in FY 1995. The Funding Preference and Priority were established in FY 1994 after public comment (at 59 FR 44740) on August 30, 1994, and are being extended in FY 1995.

Criteria for Undergraduate Students

In the instance of (3)(b) above, it has been established that the undergraduate students eligible for scholarships must be at feeder schools and have signed statements that they are interested in health professions or nursing careers.

Definitions

"Black" means a person having origins in any of the black racial groups of Africa.

"Hispanic" means a person of Mexican, Puerto Rican, Cuban, Central or South American or other Spanish culture or origin, regardless of race.

"American Indian or Alaskan Native" means a person having origins in any of the original peoples of North America, and who maintains cultural identification through tribal affiliation or community recognition.

Definitions listed above are contained in Directive No. 15 of Office of Management and Budget Circular No. A-46, dated May 3, 1974.

"Native American" as defined in Pub. L. 101-527, means American Indian, Alaskan Native, Aleut, or Native Hawaiian.

"Minority" with respect to faculty, refers to Blacks, Hispanics, Native Americans, Filipinos, Koreans, Pacific Islanders, and Southeast Asians whose percentage among the total supply of practitioners in the applicable health profession is below that group's percentage in the total population.

Methodology for Implementing the Statutory Special Consideration

In accordance with the statute, in making awards under section 737(a), the Secretary shall give special consideration to eligible schools that have enrollments of underrepresented minorities above the national average for its particular discipline.

For purposes of determining eligibility of a school, Asians will not be included in the definition of underrepresented minorities for the school. Although certain Asian subgroups (i.e., Filipinos, Koreans, Pacific Islanders, and Southeast Asians) are considered to be underrepresented in the health professions and are included as minorities for purposes of program requirements relating to faculty recruitment and retention (see above), national data on these subgroups are not available as a basis for establishing national average enrollment of underrepresented minorities.

For purposes of the FY 1995 award cycle, the national average enrollments of Blacks, Hispanics, and Native Americans (in combination) are: for medicine 13.3 percent; osteopathic medicine 7.7 percent; nursing (RN only) 12.2 percent; dentistry 13.4 percent; pharmacy 10.6 percent; optometry 9.4 percent; podiatric medicine 17.9 percent; veterinary medicine 5.9 percent; public health 15.7 percent; allied health 17.3 percent; and clinical psychology 13 percent.

Nonstatutory Special Consideration for Baccalaureate Nursing Programs

Among schools of nursing, additional special consideration will be given to baccalaureate programs. One of the distinguishing features of baccalaureate education is the substantial focus on preparation for community health practice. Training nurses for community health practice is an integral component of the Department's access strategy.

It is not required that new applicants request consideration for a funding factor. Applications from new schools which do not request consideration for funding factors will be reviewed and given full consideration for funding.

Procedures for Calculating Awards

Awards to eligible schools will be calculated by comparing the enrollment of disadvantaged students in each eligible school with the total enrollment of the disadvantaged students in all eligible schools.

A school with an enrollment of underrepresented minority students which is above the national average (for each discipline) will be given double credit (i.e., its enrollment of disadvantaged students would be doubled for awarding purposes). A baccalaureate nursing school will be given double credit. A baccalaureate nursing school with an underrepresented minority enrollment above the national average will be given quadruple credit (i.e., its enrollment of disadvantaged students will be multiplied by four for awarding purposes).

Other Considerations

Other funding factors may be applied in determining the funding of eligible schools.

A funding preference is defined as the funding of a specific category or group of eligible schools ahead of other categories or groups of eligible schools.

A funding priority is defined as the favorable adjustment of aggregate review scores of individual approved applications when applications meet specified criteria.

It is not required that new applicants request consideration for a funding factor. Applications from new schools which do not request consideration for funding factors will be reviewed and given full consideration for funding.

Funding Preference and Priority

For fiscal year 1995, among allied health schools or programs, preference will be given to the following baccalaureate and graduate programs: dental hygiene, medical laboratory technology, occupational therapy,

physical therapy and radiologic technology. In addition, priority among allied health applicants will be given to dental hygiene. A priority for dental hygiene will be implemented by taking the total funds allocated to the allied health disciplines in the initial allocation and recalculating this part of the allocation. Dental hygiene schools will receive double credit for their disadvantaged enrollments in the reallocation of the allied health funds.

National Health Objectives for the Year 2000

The Public Health Service is committed to achieving the health promotion and disease prevention objectives of Healthy People 2000, a PHS-led national activity for setting priority areas. The Scholarships for Disadvantaged Students program is related to the priority area of Educational and Community-Based Programs. Potential applicants may obtain a copy of Healthy People 2000 (Full Report; Stock No. 017-001-00474-0) or Healthy People 2000 (Summary Report; Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, D.C. 20402-9325 (Telephone (202) 783-3238).

Smoke-Free Workplace

The Public Health Service strongly encourages all grant recipients to provide a smoke-free workplace and promote the non-use of all tobacco products, and Public Law 103-227, the Pro-Children Act of 1994, prohibits smoking in certain facilities that receive Federal funds in which education, library, day care, health care, and early childhood development services are provided to children.

Paperwork Reduction Act

The application form and instructions for this program have been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act. The OMB clearance number is 0915-0149.

Application Requests

Applications are not required from schools of medicine, osteopathic medicine, dentistry, pharmacy, optometry, podiatric medicine, veterinary medicine, nursing, public health, clinical psychology and allied health which received SDS awards in FY 94. Upon request, applications will be mailed to schools in the disciplines identified above which did not participate in the SDS program in FY 94.

Requests for grant application materials and questions regarding business management and program policy should be directed to: Mr. Bruce Baggett, Chief, Student and Institutional Support Branch, Division of Student Assistance, Bureau of Health Professions, Health Resources and Services Administration, Parklawn Building, Room 8-34, 5600 Fishers Lane, Rockville, Maryland 20857. Telephone: (301) 443-4776; FAX: (301) 594-6911.

The application deadline date for new schools is August 17, 1995.

Applications shall be considered as meeting the deadline if they are either:

- (1) *Received on or before* the established deadline date, or
- (2) *Sent on or before* the established deadline and received in time for orderly processing. (Applicants should request a legibly dated U.S. Postal Service postmark or obtain a legibly dated receipt from a commercial carrier or the U.S. Postal Service. Private metered postmarks shall not be acceptable as proof of timely mailing.)

Late applications not accepted for processing will be returned to the applicant.

The *Catalog of Federal Domestic Assistance* Number for the Scholarships for Disadvantaged Students program is 93.925. This program is not subject to the provisions of Executive Order 12372, Intergovernmental Review of Federal Programs (as implemented through 45 CFR part 100).

This program is not subject to the Public Health System Reporting Requirements.

Dated: July 12, 1995.

Ciro V. Sumaya,
Administrator.

[FR Doc. 95-17556 Filed 7-17-95; 8:45 am]

BILLING CODE 4160-15-P

"Low Income Levels" for Health Professions and Nursing Programs

The Health Resources and Services Administration (HRSA) is updating income levels used to identify a "low income family" for the purpose of providing training for individuals from disadvantaged backgrounds under various health professions and nursing programs included in titles VII and VIII of the Public Health Service Act (the Act).

The Department periodically publishes in the **Federal Register** low income levels used by the Public Health Service for grants and cooperative agreements to institutions providing training for individuals from disadvantaged backgrounds. A "low

income level" is one of the factors taken into consideration to determine if an individual qualifies as a disadvantaged student for purposes of health professions and nursing programs.

The programs under the Act that use "low income levels" as one of the factors in determining disadvantaged backgrounds include the Health Careers Opportunity Program, section 740, the Program of Financial Assistance for Disadvantaged Health Professions Students, section 740(a)(2)(F), and Nursing Education Opportunities for Individuals from Disadvantaged Backgrounds, section 827. Loans to Disadvantaged Students, section 724, Scholarships for Health Professions Students from Disadvantaged Backgrounds, section 737, Disadvantaged Health Professions Faculty Loan Repayment and Fellowships Program, section 738 were added to title VII by the Disadvantaged Minority Health Improvement Act of 1990 (Pub. L. 101-527) and are also using the low income levels. Other factors used in determining "disadvantaged backgrounds" are included in individual program regulations and guidelines.

Health Careers Opportunity Program (HCOP), Section 740

This program awards grants to accredited schools of medicine, osteopathic medicine, public health, dentistry, veterinary medicine, optometry, pharmacy, allied health, podiatric medicine, chiropractic and public or nonprofit private schools which offer graduate programs in clinical psychology, and other public or private nonprofit health or educational entities to assist individuals from disadvantaged backgrounds to enter and graduate from health professions schools.

Financial Assistance for Disadvantaged Health Professions Students (FADHPS), Section 740(a)(2)(F)

This program awards grants to accredited schools of medicine, osteopathic medicine, and dentistry to provide financial assistance to individuals from disadvantaged backgrounds who are of exceptional financial need, to help pay for their health professions education. The provision of these scholarships shall be subject to section 795 relating to residency training and practice in primary health care.